

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Applicants: S. NAKATA et al. Confirmation No.: 3025
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For: AUTOMATIC ANALYZING APPARATUS
Group: 1743
Examiner: L. Alexander

REPLY BRIEF

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November 4, 2008

Sir:

This Reply Brief is responsive to the Examiner's Answer dated September 4, 2008. In accordance with 37 CFR §41.41, the Appellants address the following items.

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I. Status of Claims:

Claims 1-3, 6 and 8-12 are currently pending. Claims 1-3, 6 and 8-12 have been finally rejected and are the subject of this appeal. Claims 4, 5, 7 and 13-15 have been canceled without prejudice or disclaimer.

II. Grounds of Rejection to Be Reviewed Upon Appeal

Claims 1-3, 6 and 8-12 are rejected under 35 U.S.C. §103(a) as being unpatentable over Fritchie et al., U.S. Patent No. 6,022,746 (Fritchie) (sic, in view of Carbonari et al., U.S. Patent No. 5,730,938 (Carbonari)).

III. Arguments

References Relied Upon by the Examiner

Fritchie et al., U.S. Patent No. 6,022,746 (Fritchie); and

Carbonari et al., U.S. Patent No. 5,730,938 (Carbonari)

Claims 1-3, 6 and 8-12 are rejected under 35 U.S.C. §103(a) as being obvious over Fritchie et al., U.S. Patent No. 6,022,746 (Fritchie) in view of Carbonari et al., U.S. Patent No. 5,730,938 (Carbonari).

Claim 1

Claim 1 recites an analysis information management method using a service center connected through communication lines to a plurality of automatic analyzing apparatuses used in a plurality of facilities. The service center has a database for storing analysis parameters related to a plurality of reagents for use in the plurality of automatic analyzing apparatuses used in the facilities.

According to the method, the service center responds to a request from one of the automatic analyzing apparatuses (“the requesting automatic analyzing apparatus”), to create a list of reagents available in the requesting automatic analyzing apparatus. The list of reagents is created from information on reagents stored in the database, and the service center supplies the list to the requesting automatic analyzing apparatus through a communication line.

Responsive to a selection of an associated reagent from the list, made by a user of the automatic analyzing apparatus, the service center transfers analysis parameters, according to which a test is to be carried out on a testing item to be analyzed using the selected reagent. The service center transfers the analysis

parameters to the requesting automatic analyzing apparatus from which the reagent was selected.

Additionally, the service center classifies and stores information including results of calibrations measured by the plurality of automatic analyzing apparatuses, results of analyses on control samples, reagents used in analyses, and analysis parameters, for tests carried out in each facility or for each automatic analyzing apparatus. The Appellants note that the results of analyses on the control samples are derived from analyses of the control samples using the same reagents in all automatic analyzing apparatuses in all facilities administered by the service center, as claimed in claim 1.

Based on the stored information on the results of analyses for each facility or for each automatic analyzing apparatus, the service center calculates a statistical standard value defined for the results of analyses on the control samples using the same reagents in all automatic analyzing apparatuses in all facilities administered by the service center.

Continuing, the method adds the selected reagent to a control sample in the automatic analyzing apparatus that initially requested creation of the list of reagents. The control sample is analyzed by the automatic analyzing apparatus, a statistical deviation for the result of analysis is calculated by the service center from the standard value, and based on the calculated statistical deviation, it is determined whether the analysis parameters used in the analysis are correct.

In accordance with these method steps, because a standard value for results of analyses on control samples using the same reagents in all automatic analyzing apparatuses in all facilities administered by the service center is calculated, and a

statistical deviation therefrom is calculated, the results can be used to verify that the analysis parameters used in the analysis are correct. This also helps determine whether there is some defect in the automatic analyzing apparatus.

As asserted previously by the Appellants (see the Reply filed May 30, 2007), Fritchie does not appear to disclose or fairly suggest a step of calculating a deviation between the results of analysis and the standard value when a control sample is newly analyzed by an automatic analyzing apparatus, or a step of using the results of this analysis to determine that the analysis parameters used in the analysis are correct. In addition, Fritchie is believed not to suggest the steps of creating and supplying the list of reagents responsive to the request, transferring analysis parameters responsive to selection of the reagent from the list, calculating the statistical standard value, or analyzing the control sample, as well as the steps of calculating the statistical deviation from the standard value for the result of the control sample analysis and determining whether the analysis parameters are correct based in the statistical deviation.

In the Examiner's Answer, the Examiner asserts that Fritchie teaches a method of allocating resources of an automated analyzer to optimize analysis, and cites col. 5, line 1-col. 7, line 37 as teaching system software that tracks reagent inventory and notifies the user as needed. According to the Examiner's answer, the "device" (apparently, the system software) also tracks the calibration status of test and lot numbers for each of the instruments 12A-12D. In addition, the Examiner's answer states that Fritchie teaches, in col. 6, lines 6-16, a system 10 that contains all of the necessary software connected to the plural instruments 12A-12D.

Although col. 6, lines 6-16 broadly disclose that the system software “supplies other inputs, including an available search range comprising dates and times, tests installed on the system 10, available test kit sizes, test results, the number of instruments 12A, 12B, 12C and 12D on-line in the system 10, and the number of reagent packs for all tests installed,” which is something less than a disclosure of “all the necessary software connected to plural instruments 12A, 12B, 12C and 12D,” the Appellants wish to focus attention on the subsequent assertion that the system 10 “has been read on the ‘service center.’”

The preamble of claim 1 recites an analysis information management method using “a service center connected through communication lines to a plurality of automatic analyzing apparatuses used in a plurality of facilities, said service center having a database for storing analysis parameters related to a plurality of reagents for use in the plurality of automatic analyzing apparatuses used in the plurality of facilities.” As noted above, the method includes the following steps performed by the service center:

creating, by said service center responsive to a request from one of said automatic analyzing apparatuses, a list of reagents available in said one automatic analyzing apparatus from information on reagents stored in said database, and supplying said one automatic analyzing apparatus with the list through a communication line;

transferring, by said service center responsive to a selection of an associated reagent from said list, made by a user of said one automatic analyzing apparatus, analysis parameters, according to which a test is to be carried out on a testing item to be analyzed using the selected reagent, to said one automatic analyzing apparatus through said communication line;

wherein said service center classifies and stores information, including results of calibrations measured by said automatic analyzing apparatuses, results of analyses on control samples, reagents used in analyses, and analysis parameters, for tests carried out in each facility or for each automatic analyzing apparatus, wherein the results of analyses on said control samples

are derived from analyses of said control samples using the same reagents in all automatic analyzing apparatuses in all facilities administered by said service center;

calculating, by said service center based on the stored information on the results of analyses for each facility or for each automatic analyzing apparatus, a statistical standard value defined for said results of analyses on said control samples using the same reagents in all automatic analyzing apparatuses in all facilities administered by said service center;

calculating, by said service center, a statistical deviation for the result of analysis from said standard value for evaluation

Manifestly, the disclosure in col. 6, lines 6-16 of system 10 is inadequate to read on the claimed service center, which performs these many steps according to the method.

To support the statement reading the system 10 on the claimed service center, the Examiner's Answer continues, stating that col. 6, lines 17-24 disclose that the data management portion generates outputs that control the various operations of the automated analyzer, and that the "instant language" is sufficiently broad to have been properly read on the taught data management portion. However, the Examiner's Answer does not identify the "instant language" that is properly read on the taught data management portion. Furthermore, lines 17-24 of col. 6 disclose that the data management portion accepts configuration data requests and tests data requests and fulfills data management requests, generating outputs including configuration and test data, supplied to the managed test distribution list portion and the generate reagent load map portion. It is not clear, though, how this disclosure is to be applied against the "instant language" of claim 1. In any event, the disclosure does not appear to be particularly pertinent to claim 1.

The Examiner's Answer continues, asserting that col. 5, lines 55-63 discloses identification of the current reagent inventory and comparison with a theoretical reagent map, which is said to meet the claimed limitations of storing database parameters relating to reagents. This alleged claim language, apparently taken from the preamble, actually states that the service center has a database for storing analysis parameters related to a plurality of reagents for use in the plurality of automatic analyzing apparatuses used in a plurality of facilities. Fritchie's identification of current reagent inventory and comparison with the theoretical reagent map does not suggest the storing of analysis parameters in a database. Furthermore, col. 5, lines 55-63 do not disclose any of the steps performed by the service center, or any other steps contained in claim 1.

The above statements contained in the Examiner's Answer constitute the entirety of the teachings of Fritchie applied against claim 1. The secondary reference to Carbonari is cited as disclosing the claimed step of calculating a statistical standard value, such that its combination with Fritchie renders obvious claim 1.

Initially, the Appellants note that the numerous steps of claim 1, distinguished from Fritchie above, cannot be rendered obvious by the combination of Fritchie and Carbonari, even if Carbonari were to disclose the claimed step of calculating a statistical standard value. Indeed, Carbonari does not even disclose the noted claimed step, which in its entirety, is the step of

calculating, by said service center, based on the stored information on the results of analyses for each facility or for each automatic analyzing apparatus, a statistical standard value defined for said results of analyses on said control samples using the same reagents in all automatic analyzing apparatuses in all facilities administered by said service center.

It is evident that this step is more than simply “calculating a statistical standard value.”

The Examiner’s Answer further asserts that Carbonari teaches a random access analyzer for automatically conducting colorimetry, photometric and other tests on biological fluids that are routinely required in a clinical environment, the analyzer automatically tracking the sample and reagents necessary to perform the tests. The Examiner’s Answer particularly cites col. 4, lines 10-18 as teaching, “A built in quality control system monitors the tests for statistical deviations. All of these and other functions and parameters are within the skill of those of ordinary skill in the art to implement.”

Respectfully, the above is the entire disclose of Carbonari with regard to statistical deviations, and falls short of the requirements of claim 1. Therefore, although the Examiner asserts that it is “known and desirable to monitor the statistical deviation of the data to determine the certainty and confidence of the results, and that such constitutes the claims “. . . calculating. . . the statistical standard value. . . calculating. . . a statistical deviation. . . determining, based on the calculated statistical deviation, whether the analysis parameters used in the analysis are correct,” it is difficult to understand how the bare disclosure of the known monitoring of tests for statistical deviations can be said to teach the person of ordinary skill to calculate the statistical standard value defined for the results of analyses on control samples using the same reagents in all automatic analyzing apparatuses in all facilities administered by the service center; adding a selected reagent to a control sample in an automatic analyzing apparatus; analyzing the control sample by the automatic analyzing apparatus; calculating, by the service

center, a statistical deviation for the result of analysis from the standard value for evaluation; and determining, based on the calculated statistical deviation, whether the analysis parameters used in the analysis are correct.

Indeed, Carbonari is primarily directed to the improved efficiency of washing the exterior and interior of a needle tip during the transfer from a reagent carrier 52 to a sample carrier 102, and from the sample carrier 102 back to the reagent carrier 52. Carbonari is not concerned with the calculation of statistical values defined for results of analyses on control samples according to claim 1, using the same reagents in all automatic analyzing apparatuses in all facilities administered by a service center. Carbonari is further not concerned with adding a selected reagent to a control sample in one of the automatic analyzing apparatuses; analyzing a control sample by the automatic analyzing apparatus; calculating, by the service center, a statistical deviation for the result of analysis from the standard value for evaluation; and determining, based on the calculated statistical deviation, whether the analysis parameters used in the analysis are correct.

Of course, the Examiner's Answer states correctly that Fritchie is silent to the claimed step of calculating a statistical standard value. It thus follows that Fritchie is silent as to the application of the statistical standard value in the calculation of a statistical deviation, as well as the determination of whether the analysis parameters used in the analysis are correct, the statistical standard value being defined for the results of analyses on control samples using the same reagents in all automatic analyzing apparatuses in all facilities administered by the service center.

Accordingly, no *prima facie* of obviousness is made out with respect to claim 1 in view of the teachings of Fritchie and Carbonari, however combined.

Claim 2

Dependent claim 2 further limits the analysis information management method of claim 1 by requiring the automatic analyzing apparatus to automatically set the transferred analysis parameters. The Examiner's Answer finds this feature in col. 6, lines 17-24, which disclose a data management portion that accepts configuration data requests and test data requests and fulfills data management requests, generating outputs, including configuration and test data, supplied to the managed test distribution list portion and the generate reagent load map portion.

This disclosure of Fritchie, however, does not pertain to an automatic analyzing apparatus which is required to automatically set analysis parameters that are transferred to one of a plurality of automatic analyzing apparatuses through a communication line, in response to the selection of an associated reagent from a list of reagents available in the automatic analyzing apparatus, wherein the selection is made by a user of the automatic analyzing apparatus, and wherein the analysis parameters are defined for a test which is to be carried out on a testing item to be analyzed using the selected reagent. Accordingly, no *prima facie* case of obviousness is established for the rejection of claim 2. The Appellants thus request reversal of the rejection of dependent claim 2.

Claim 3

Dependent claim 3 further limits the analysis information management method of claim 1 by requiring the database stored in the service center to store analysis parameters related to reagents from a plurality of reagent suppliers. The Examiner's answer addresses this claim by citing col. 5, lines 55-63 of Fritchie, and its alleged

disclosure of identification of the current reagent inventory and comparison with a theoretical reagent map.

However, col. 5, lines 55-63 disclose that the reagent loading portion of the allocation method of Fritchie compares the theoretical reagent map with the reagent inventory, identifies reagent packs to be removed from the instruments 12A-12D, identifies reagent packs to be loaded on the instruments 12A-12D, identifies additional calibrations to be performed on the instruments 12A-12D, and maintains inventory based on the theoretical reagent load map. This passage thus does not suggest a database, stored in a service center, that stores analysis parameters related to reagents from a plurality of reagent suppliers. Accordingly, the Examiner's Answer does not establish a *prima facie* case of unpatentability of claim 3, and thus reversal of the rejection of claim 3 is respectfully requested.

Claim 6

Dependent claim 6 further limits the analysis information management method of claim 1 by requiring that, when a reagent supplier supplies a novel reagent or a reagent in a new lot to a user of the requesting automatic analyzing apparatus, the reagent supplier registers the database stored in the service center with information related to the reagent, such as the reagent, automatic analyzing apparatuses capable of using the reagent, and analysis parameters for the reagent prior to supply. In the Appeal Brief, the Appellants asserted that the Final Rejection does not address any of these limitations of claim 6 with specificity.

In reply, the Examiner's Answer condenses this argument to a statement that "Fritchie fails to teach the claimed method of registering a new reagent in the analyzer." Such, however, ignores the precondition that a reagent supplier supplies

a novel reagent or a reagent in a new lot to a user of the requesting automatic analyzing apparatus, whereupon the reagent supplier registers the database stored in the service center with information related to the reagent, such as the reagent, automatic analyzing apparatuses capable of using reagent, and analysis parameters for the reagent prior to supply. On this basis, at least, the rejection of claim 6 should be reversed because the Examiner's Answer continues to fail to address the limitations of claim 6 with the required specificity.

In addition, the Examiner's Answer asserts that the disclosure of "identifying the reagent packs loaded into the analyzer" in col. 5, lines 55-63 of Fritchie is sufficient to render obvious the limitations of claim 6. However, this passage is quoted above in arguing against the rejection of claim 3, and clearly does not address the limitations of claim 6. Specifically, the identification of reagent packs to be loaded on the instruments 12A-12D does not address the precondition or the result set forth in claim 6. Accordingly, no *prima facie* case of unpatentability is made out, and the rejection of claim 6 should thus be reversed.

Claim 8

Dependent claim 8 further limits the analysis information management method of claim 1 by requiring the service center, upon determination that the result of analysis on an accuracy management sample transferred thereto from the automatic analyzing apparatus was derived using newly set analysis parameters, to summarize the result of determination in a report, and to transmit the report to the automatic analyzing apparatus through the communication line.

In the Examiner's Answer, Carbonari is cited as teaching the limitations of claim 8. In particular, the Examiner's Answer simply states that Carbonari teaches

“a quality control system that calculates statistical deviation, and thus renders obvious the invention claimed in claim 8.” However, as noted, claim 8 requires the precondition of determining that the result of analysis on an accuracy management sample transferred to the service center from the automatic analyzing apparatus be derived using newly set analysis parameters, whereupon the service center summarizes the results of determination in a report, and transmits the report to the automatic analyzing apparatus through a communication line. The bare disclosure in Carbonari of “monitor(ing) the tests for statistical deviations” does not address any of the limitations of claim 8. Accordingly, any motivated combination of Fritchie and Carbonari cannot be said to render obvious claim 8, and thus the Appellants respectfully request reversal of the rejection.

Claim 9

Dependent claim 9 further limits the analysis information management method defined in claim 1, by requiring that each time the service center receives the result of analysis on a control sample from the requesting automatic analyzing apparatus, the service center calculates the statistical deviation from the standard value, and transmits the results of analysis to the requesting automatic analyzing apparatus through the communication line if any defect is recognized based on the determination.

In the Examiner’s Answer, col. 5, lines 55-63 of Fritchie are again applied. Particularly, the disclosure in this passage of “additional calibrations . . . performed on the instruments 12A, 12B, 12C and 12D”, in combination with Carbonari’s “quality control system [that] monitors the tests for statistical deviations” should be found to render obvious claim 9. However, neither Fritchie nor Carbonari discloses, in the

cited passages or anywhere else in these documents, that each time the service center receives the result of analysis on a control sample from a requesting automatic analyzing apparatus, the service center calculates the statistical deviation from the standard value, and transmits the results of analysis to the requesting automatic analyzing apparatus through a communication line if any defect is recognized based on the determination. Accordingly, no *prima facie* case of unpatentability is made out, and thus the reversal of the rejection claim 9 appears to be warranted.

Claim 10

Dependent claim 10 further limits the analysis information management method of claim 9 by requiring that, when no defect is recognized in the result of analysis, the service center stores the result of analysis, periodically creates a report, and transmits the report to the automatic analyzing apparatuses through the communication lines.

The Examiner's answer addresses this claim by citing, again, to Carbonari's bare disclosure of a calculation of statistical deviations, which allegedly "would save the valid data." This assertion does not address the precondition that no defect is present, or the result that the service center stores the result of analysis, periodically creates a report, and transmits the report to the automatic analyzing apparatuses through communication lines. Accordingly, no *prima facie* case of unpatentability is made with respect to claim 10, and thus the Appellants respectfully request reversal of the rejection.

Claim 11

Dependent claim 11 further limits the analysis information management method of claim 1, by requiring the service center to periodically calculate the standard value, and to transmit the standard value to the automatic analyzing apparatuses through the communication lines as technical information.

The Examiner's Answer asserts that Carbonari teaches the additional limitations of claim 11 with respect to Carbonari's quality control system said to calculate statistical deviations. However, claim 11 requires the service center to periodically calculate the standard value, and to transmit the standard value to the automatic analyzing apparatuses through the communication lines as technical information. Thus, the Examiner's Answer repeats the failure of the Final Rejection to properly address the limitations of claim 11, such that no *prima facie* case of unpatentability is established. Accordingly, the Appellants respectfully request reversal of the rejection of claim 11.

Claim 12

Dependent claim 12 further limits the analysis information management method of claim 1 by requiring the service center to store and manage, by version, programs for controlling the automatic analyzing apparatuses administered thereby, and to automatically install a program of a requested version in response to a request from an automatic analyzing apparatus administered thereby.

Against this claim, the Examiner's Answer asserts col. 6, lines 6-16 of Fritchie as teaching a system that contains all of the necessary software connected to the plural instruments 12A-12D. This passage only broadly discloses software that "supplies other inputs, including an available search range comprising dates and

times, tests installed on the system 10, available test kit sizes, test results, the number of instruments 12A, 12B, 12C and 12D on-line in the system 10 and the number of reagent packs per test for all tests installed." Thus, the limitations of claim 12 are not addressed at all in the Examiner's Answer. Accordingly, the Appellants respectfully request reversal of the rejection of claim 12.

IV Conclusion

Although the Examiner's Answer properly indicates that the Appellants have the option to reopen prosecution in accordance with the new grounds of rejection, the Appellants opt instead to maintain the appeal by filing this Reply Brief, addressing the new grounds of rejection.

For the foregoing reasons, the Appellants respectfully submit that the rejection of the claims on Appeal should be reversed and the application allowed.

Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, or credit any overpayment of fees, to the deposit account of Mattingly, Stanger, Malur & Brundidge, P.C., Deposit Account No. 50-1417 (referencing attorney docket no. KAS-157).

Respectfully submitted,

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